UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
DOCKET NO. 3:11-cv-00406-FDW

MERIDIAN LABORATORY CORPORATION,	)	
Plaintiff,	)	
vs.	)	**ORDER**
THE HONORABLE KATHLEEN SEBELIUS, SECRETARY,	)	
Defendant.	)	

THIS MATTER comes now before the Court upon cross-motions for summary judgment filed by Plantiff Meridian Labortory Corporation ("Plaintiff") and Defendant Kathleen Sebelius in her official capacity as Secretary ("the Secretary") of the U.S. Department of Health and Human Services ("HHS"). (Doc. Nos. 15, 17). Both parties have responded and replied, the Court has heard oral argument, and this matter is now ripe for review. For the reasons below the Court REMANDS this matter for review in accordance with the following opinion and DENIES AS MOOT both motions.

PROCEDURAL BACKGROUND

In 2006, pursuant to standard Medicare procedure, Program Safeguard Contractor ("PSC") AdvanceMed opened an investigation into the billing pratices of Plaintiff Meridian Laboratory Corporation, a clinical diagnostic laboratory that administers regular kidney dialysis treatment to patients suffering from end-stage renal disease ("ESRD"). See 42 U.S.C. § 1395ddd (2011) (statute creating the Medicare Integrity Program and PSC's investigative authority); Meridian Laboratory Corp., Decision of Medicare Appeals Council 3, June 24, 2011 [hereinafter "MAC Decision"], A.R.

4. As a result of the audit and an unfavorable Medicare coverage determination, Plaintiff followed the five-step appeals process, created by the Medicare Act ("the Act"), 42 U.S.C. §§ 1395 et seq. (2012), for dissatisfied claimants, as set out below. After seeking a "redetermination" from the preliminary contractor, a claimant can request for a "qualified independent contractor" ("QIC") to "reconsider" the initial determination. Id. § 1395ff (b), (c). The QIC makes "a decision . . . based on applicable information, including clinical experience and medical, technical, and scientific evidence," unless an applicable "national coverage determination" ("NCD") or "local coverage determination" ("LCD") governs the claim. Id. § 1395ff(c)(3)(B)(ii)(III). Next, a claimant can request a hearing by an administrative law judge ("ALJ") for a review of the QIC's decision. Id. § 1395ff(d)(1). The claimant's fourth step is an appeal to the Medicare Appeals Council ("MAC"). Id. § 1395ff(d)(2). If still unsatisfied, the party can bring a final action in federal court. Id. § 1395(b)(1)(A).

Generally, Medicare Part B covers diagnostic laboratory tests that are "reasonable and necessary for the diagnosis or treatment of illness or injury . . ." Id. § 1395y(a)(1)(A). Tests not listed in the NCD are covered only with appropriate documentation, see 42 U.S.C. § 1395l(e); 42 C.F.R. § 410.32 (2011); additionally, the tests are subject to the "reasonable and necessary" requirements found in the Medicare Act. Id.

FACTUAL BACKGROUND

Plaintiff's primary patient population suffers from ESRD, an advanced condition that necessitates tri-weekly treatment, and physicians in the case at bar issued standing orders to authorize dialysis.[1] See Plaintiff's Motion for Summary Judgment, Doc. No. 10, 1-2. Plaintiff's

[1]Plaintiff has argued throughout the entire appellate process that standing orders are appropriate when a medical condition requires frequent treatment. See Plaintiff's Motion for

frequent treatment of this "discreet patient population" resulted in "aberrant" billing numbers in comparison to similar treatment facilities. See MAC Decision, supra at 3, A.R. 4. AdvanceMed's aforementioned audit of Plaintiff's reimbursed claims found a $4.1 million overpayment for tests that fell outside the applicable NCD.[2] Id. Plaintiff's request for redetermination resulted only in a reduction of the amount to slighty under $4 million. Id. At reconsideration, the QIC determined that "the record contained insufficient documentation to justify medical necessity for additional laboratory work 'above and beyond monthly ESRD composite panel,'" therefore, Medicare did not cover the extra tests. Id. at 4, A.R. 7.

Upon appeal, the ALJ remanded the case, finding in part that in order to preserve Plaintiff's due process rights, the QIC must allow it additional time to obtain proper documentation of medical necessity from the ordering physician. Id. About seven months later, the QIC issued an amended unfavorable decision and Plaintiff filed a second request for an ALJ hearing. Id. at 5, A.R. 8. On October 29, 2010, after conducting a telephonic hearing, the ALJ issued a fully favorable decision, holding that Plaintiff's ordering procedures and "physician attestations" to the usefulness of the tests met the legal standard for medical necessity found in 42 C.F.R. § 410.32. MAC Decision, supra at 6, A.R. 9.

CMS referred the case to the MAC, which found that "the ALJ erred in concluding that the medical necessity of the diagnostic laboratory tests claims was established." Id. at 17, A.R. 20. The additional tests were not "considered routinely associated with the needs of a dialysis patient"and

---

Summary Judgement, Doc. No. 10, 6-7. The Court does not make a finding regarding the propriety of standing orders at this time.

[2]The applicable NCD can be found in the National Coverage Determination Manual, Ch. 1, § 190.10.

decided that the tests must be *ordered* and the results *used* by the treating physician in order for them to qualify as medically reasonable and necessary. Id. at 18, A.R. 21. The standing orders used in the claims at issue did not suggest immediate physician involvement in the tests or reliance on the results, and therefore did not meet the medical necessity statutory requirement. Id. at 18-19, A.R. 21-22. See 42 C.F.R.§ 410.32 (2011). MAC completely reversed the ALJ decision. Id. at 18-19, 23; A.R. 21-22, 26.

On appeal, Plaintiff claims that the MAC wrongly undertook a *de novo* review of the ALJ's decision, rather than restricting its findings to errors of law as required by 42 C.F.R § 405.1110(c) (2011). Plaintiff's Motion for Summary Judgment, Doc. No. 10, 14. Further, Plaintiff claims that even if this Court upholds the MAC's determination of medical reasonableness and necessity, it is entitled to a limitation of liability pursuant to 42 U.S.C. § 1395pp. Plaintiff's Motion for Summary Judgment, Doc. No. 10, 17. Plaintiff also asserts that the Secretary made an "arbitrary and capricious" delegation of authority by allowing AdvanceMed to define and determine the existence of the "sustained or high level of payment error in this case." Id. at 16. Finally, Plaintiff contends that the procedural difficulties it has encountered throughout this appeals process have violated its due process rights. Id. at 17.

STANDARD OF REVIEW

When reviewing the Secretary's final decision, this Court bases its decision solely on the administrative record. The Secretary's findings of fact are conclusive, if supported by substantial evidence. MacKenzie Med. Supply, Inc. v. Leavitt, 506 F.3d 341, 346 (4th Cir. 2007) (citing 42 U.S.C. § 1395ff(b)(1)(A) (2011) (incorporating 42 U.S.C. § 405(g) by reference)). Agency actions will be set aside if they are found to be (1) "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;'" (2) "'in excess of statutory jurisdiction, authority, or

limitations, or short of statutory right;'" or (3) "'without observance of procedure required by law.'" West Virginia v. Thompson, 475 F.3d 204, 209 (4th Cir. 2007) (quoting the Administrative Procedure Act, 5 U.S.C. § 706(2) (2006)).

The Supreme Court defined substantial evidence as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consolo v. Fed. Maritime Comm'n, 383 U.S. 607, 619-20 (1966) (quotation omitted); see Mastro v. Apfel, 270 F.3d 171, 176 (4th Cir. 2001). Therefore, the court does not weigh evidence or make factual findings, and it does not "substitute its judgment for that of the agency." Thompson, 475 F.3d at 212. Further, the "arbitrary and capricious" standard is a "highly deferential standard which presumes the validity of the agency's action." Natural Resources Defense Council v. EPA, 16 F.3d 1395, 1400 (4th Cir. 1993). Therefore, the Secretary's interpretation of the Medicare statute and additional regulations is entitled to substantial deference. See Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), Thomas Jefferson Univ. v. Shalala, 512 U.S. 504 (1994), District Mem'l Hosp. of Sw. N.C. v. Thompson, 364 F.3d 513, 518 (4th Cir. 2004).

ANALYSIS

The Code of Federal Regulations authorizes the MAC to review ALJ decisions *sua sponte* to correct legal errors or address broad policy issues that arise below. See 42 C.F.R. § 405.1110 (2010) ("The MAC will accept review if the decision or dismissal contains an error of law material to the outcome of the case . . ."); see also MAC Decision, supra at 1, A.R. 4 ("The [MAC] has decided, on its own motion, to review the [ALJ's] decision . . . because there is an error of law material to the outcome of the claims."). The primary dispute between the parties here relates to the standard the MAC used during said review of the ALJ, but this Court finds that question presently unanswerable. Due to a substantial omission in the record discussed in detail below, this Court

cannot determine the propriety of the MAC's decision and refrains from exercising its appellate jurisdiction until the error is rectified.

At the outset of its review, the ALJ wrote that if Plaintiff's services were denied coverage, "an additional issue arises as to whether Medicare payment may be made under the limitations of liability provisions of § 1879 of the Act." Meridian Laboratory Corp., Administrative Law Judge Decision 2, October 29, 2010 [hereinafter "ALJ Decision"], A.R. 655. See 42 U.S.C. § 1395pp (2011) (limiting the liability of service providers if the services are not found to be reasonable and necessary and the provider did not or could not reasonably have been expected to know that the services were not covered). Since the ALJ found that the services warranted coverage, it did not reach the limited liability issue. Even though the MAC reached a different conclusion on appeal, the ALJ's mention of the issue obliged the MAC to address it.

The MAC foundered in this regard. Its decision lists § 1879 of the Act in the "Applicable Legal Standards" section, and later re-states the statute as a basis of Meridian's liability. See MAC Decision, supra at 16, 24; A.R. 19, 27. However, nowhere else does the MAC address limited liability in detail even though it found "that the services provided do not meet Medicare coverage requirements and are not covered by Medicare." MAC Decision, supra at 1, A.R. 4. The Court finds that the MAC must address this deficiency before it can reach a decision on any other issues presented.

At this time, the Court does not make a determination as to the propriety of MAC's standard of review or appellate jurisdiction. However, if the MAC did appropriately find a legal error, its reversal of the ALJ creates a new issue of limited liability that it must address upon remand. At oral argument, the Secretary conceded that remand on the question of limited liability was appropriate. See Transcript of Oral Arguments, Doc. No. 26, p. 33-35. The Court also notes that an explicit

ruling on the issue of limited liability by the MAC could render all other issues moot. Therefore, this Court advises the MAC to award or deny Plaintiff a limitation of liability; if the MAC finds that question is not in its 405(c) *sua sponte* jurisdiction, it should request an ALJ decision on the issue. In short, this Court directs that the Secretary present a complete record before the Court makes any decisions as to the procedures used below or the merits of the case in general.

CONCLUSION

For the reasons stated above, the Court REMANDS this matter for review in accordance with this Order and DENIES AS MOOT both Plaintiff and Defendant's Motions for Summary Judgment. The Clerk is respectfully directed to CLOSE the case.

IT IS SO ORDERED.

Signed: July 31, 2012

Frank D. Whitney
United States District Judge

Signed: July 31, 2012

Frank D. Whitney
United States District Judge